

Date 9-25-99

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Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: 99P-1340/CP 1
Petition to Have "Eternity eau de parfum" Misbranded

Dear Sir or Madam:

I am writing to you concerning the petition submitted in May, 1999 by the Environmental Health Network (EHN) to have Calvin Klein's "Eternity eau de parfum" declared misbranded. I support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 specifically states:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning—The safety of this product has not been determined."

Results of recent testing on "Eternity" show that the perfume contains irritants, sensitizers, ingredients capable of causing central nervous system, fetal, and reproductive effects, ingredients that are suspected of causing cancer, ingredients that are considered toxic, and ingredients whose chemical, physical, and toxicological properties have not been thoroughly investigated. Yet, "Eternity" does not carry a warning label per FDA regulations.

Most consumers assume that because a product is on the market, it has been thoroughly tested and found to be safe for use. They are unaware that fragrances have only limited safety testing and that the FDA does not require products to be tested before being placed on the market. Also, most consumers do not know that the manufacturers are not required to test their products for safety—products intended to be inhaled and applied to the skin, and which are absorbed into the body. Once the chemicals in the fragrances have found their way into the bloodstream via inhalation or absorption or by way of the eyes, they can affect the brain, lungs, and other organs, and have even been found to be stored in fat cells and in breast milk. Most people think these are harmless products and are safe to use in any setting. They feel that if a product was really

99P-1340

C 477

harmful, some governmental agency would not allow it to be on the market for sale.

Consumers, as well as the people who's health has been adversely affected by second-hand exposure to fragrances, do not have the opportunity to learn what ingredients are in fragrance products since manufacturers are protected by "trade secret" laws and therefore, are not required to disclose the ingredients. We have a right to be informed about neurotoxic and carcinogenic ingredients as well as ones that are capable of causing respiratory problems and reproductive problems in products such as "Eternity" so we can protect ourselves and our families from toxic chemicals that may cause health problems.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people including: people with asthma, allergies, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, care givers, and teachers. Those who involuntarily inhale the fragrances of others suffer needlessly.

Please enforce your existing regulations on behalf of the millions of people who suffer physical illness and injury resulting from fragrance exposure at work, at school, in medical treatment facilities, and in social settings. Toxic chemicals in fragrances act as powerful barriers to people disabled by asthma and chemical sensitivities. Thank you for your consideration.

Sincerely,

Richard L. Entchev

Signature (Required)

108 S. GOLIAD

(address)

BIG SPRING TX 79720

(city, state, zip)